K093805

510(k) Summary

FEB 19 2010

OSCAR 3

Common Name:	Ultrasonic Surgical Instrument
Classification Name:	Instrument, Surgical, Sonic And Accessory/Attachment
Product Code:	JDX and LZV
Sponsor:	Orthosonics Ltd Bremridge House Ashburton Devon TQ13 7JX UK T: +44 1364 652426 F: +44 1364 653589
Contact:	Dr. Michael J.R. Young,

A. REASON FOR SUBMISSION

This 510(k) is being filed to obtain clearance to market the OSCAR 3.

B. LEGALLY MARKETED PREDICATE DEVICES

This premarket notification will demonstrate that the OSCAR 3 is substantially equivalent to the Orthosonics OSCAR OE3000DB cleared by FDA as K051053 and the Orthosonics OSCAR Bone Resector (K083830).

C. DEVICE DESCRIPTION

The OSCAR 3 system consists of a generator, 3 handsets, an optional trolley and a range of single use and reusable probes. The generator is effectively an integration of the OSCAR OE3000DB and OSCAR Bone Resector generators. It comprises 3 channels, 2 of which are designed to provide power to the handsets from OSCAR OE3000DB and the third channel is dedicated to provide power to the handset from the OSCAR Bone Resector. The handsets and probes are identical to those of the predicate devices.

D. INTENDED USE

The Orthosonics OSCAR 3 is intended to be used for cutting and removal of bone and polymethylmethacrylate (PMMA) bone cement in orthopedic applications.

E. TECHNOLOGICAL CHARACTERISTICS

The basic technological characteristics of the OSCAR 3 are the same as those of the predicate devices. Both OSCAR 3 and Orthosonics OSCAR OE3000DB systems are designed to use ultrasound to cut bone and bone cement during orthopedic surgery. The main difference is that the OSCAR 3 system also incorporates the ability to drive the handset from the OSCAR Bone Resector. In addition an optional dedicated trolley can be supplied for use with the OSCAR 3.

F. SUBSTANTIAL EQUIVALENCE SUMMARY

OSCAR 3 uses the same handsets and the same probe range in the same mode as the predicate devices. It has the same intended use as the OSCAR OE3000DB.

However, the descriptive characteristics may not be sufficiently precise to assure substantial equivalence. Therefore, performance testing was carried out for some characteristics. The data from this testing are available and are presented in this 510(k). The data do in fact demonstrate equivalence.

G. TESTING

Testing to FCC Part 18 will be carried out prior to marketing the device in the USA. Electrical testing to UL 60601-1 will be carried out by Underwriters Laboratories before marketing the device in the USA.

H. CONCLUSIONS

This premarket notification has demonstrated substantial equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

FEB 19 2010

Orthosonics Ltd.
% Michael J.R. Young, Ph.D.
Managing Director
Bremridge House
Ashburton
Devon TQ13 7JX, United Kingdom

Re: K093805
Trade/Device Name: OSCAR 3
Regulation Number: 21 CFR 888.4580
Regulation Name: Sonic surgical instrument and accessories/attachments
Regulatory Class: Class II
Product Code: JDX, LZV
Dated: December 07, 2009
Received: December 11, 2009

Dear Dr. Young:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

ACTING DSORD DIR.

FOR Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093805

Device Name: OSCAR 3

Indications For Use:

The Orthosonics OSCAR 3 is intended to be used for cutting and removal of bone and acrylic bone cement in orthopedic applications.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FOR M. MELKERSON

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093805